

REMARKS

Applicants believe no new matter is added by this amendment. This amendment is being made in response to the final Office action and was not made previously for that reason.

Amendments to the claims.

Applicants believe that the present amendments do not raise new issues. Claims to methods for producing transgenic plants that express polypeptides with at least 85% identity to SEQ ID NO: 4, where the plants are more tolerant to salt or osmotic stress than a control plant (e.g., in the amendment of July 27, 2009, claim 69). See also the response of September 15, 2008, claim 47: "selecting a transgenic progeny plant that is more tolerant to salt than the control plant". Previous examination of these claims would elucidate art related to methods for producing plants expressing polypeptides with at least 95% identity to SEQ ID NO: 4 with the properties of greater tolerance to salt or osmotic stress, and increased yield.

Claims 1-61 were canceled in previous amendments. Claims 62-77 are presently canceled. New claims 78-98 are added. After entry of the instant amendment, claims 78-98 will remain pending. Applicants believe that present amendments place this application in better condition for appeal or allowance.

Support for the amendments to the claims may be found, for example, with the following disclosures for producing and selecting a plant that overexpresses the G482 (SEQ ID NO: 4) sequence and has greater tolerance to an osmotic stress or enhanced yield:

on page 8, lines 7-12: "This method is performed by selecting a polynucleotide that encodes the G482 polypeptide (SEQ ID NO: 4), inserting either this polynucleotide or its complement into an expression cassette (for example, the expression cassette described above), introducing the expression cassette into a plant or plant cell in order to overexpress the G482 polypeptide, which thereby produces a plant having increased tolerance to osmotic stress. A plant that has this increased tolerance relative to a control plant not so transformed may then be identified and selected"; and

page 74, lines 12-13: "Following transformation, plants are preferably selected using a dominant selectable marker incorporated into the transformation vector. After transformed plants are selected and grown to maturity, those plants showing a modified trait are identified. The modified trait can be any of those traits described above" [salt tolerance and yield are described above this on, for example, page 69, lines 27-29: "In particular, increased salt tolerance during the germination stage of a plant enhances survival and yield", and osmotic stress is described in the paragraph on page 68 beginning at line 5]; and

support for the amendments to the claims for the claim element of at least 95%, or 98%, identity to SEQ ID NO: 4 may be found, for example, with the disclosure on page 40 at lines 6-8.

Response to specific items in the Office action

Item 3. Priority

The latest Office action bases the Office's non- recognition of U.S. Provisional Application 60/125,814 as a relevant priority document on the argument in previous Office action mailed 15 October 2009, which asserts that none of the arguments or submissions by Applicants were persuasive: "none of these show that Applicants conceived of plants comprising a nucleic acid encoding SEQ ID NO: 14 (sic; it is believed the Examiner means to refer to SEQ ID NO: 4) and that had a known utility. Further, none of this evidence shows that this Applicant even possessed SEQ ID NO: 14 at that time – oligonucleotides and a partial sequence are not SEQ ID NO: 14 or a nucleic acid encoding it. Further, evidence that Applicant did not possess SEQ ID NO: 14 is that it is not present in 60/125,814."

However, Applicants appreciated that a slightly truncated SEQ ID NO: 4 (NCBI accession no: Y13724) in the earlier 60/125,814 application may be transformed into plants and provide utility. Please see the first paragraph of 60/125,814: "this invention relates to recombinant constructs for the regulation of gene expression in plants and for effecting changes in plant phenotype".

Applicants also disclosed in 60/125,814 that the sequences provided therein may be transformed into plants to affect their phenotype e.g., claims 1 and 2, to provide useful traits: "In one aspect, the invention provides a recombinant construct which when introduced in a plant alters the phenotype of the plant. Of particular interest, are changes in seed phenotype. Desirable changes in a seed's phenotype include its germination characteristics; shelf-life; drydown characteristics; size; stress responses, such as to heat, cold, *salt or osmotic shock*; protein, oil or starch content; other nutritional content, such as vitamins, minerals, flavonoids, phytosterols or phytic acid; seedling vigor; insect resistance, seed coat quality or the like. Alternatively, the changes may occur in fruit, seeds, roots, flowers, leaves, shoots, seedlings or in combinations of such tissue. And desirable phenotypic changes include increased pest or insecticide resistance, increased plant biomass, resistance to environmental stresses or the like" (60/125,814, beginning at page 1, line 30, *emphasis added*).

Applicants disclosed that the specific sequence described in 60/125,814 on March, 23, 1999 is a transcription factor in the attached appendix listing the nucleic acid and polypeptide sequences: "Y13724[AtHAP3b Arabidopsis thaliana mRNA for Hap3b *transcription factor*" (*emphasis added*). The USPTO itself recognizes that nucleotides that encode a protein that alters expression have utility: a "claimed DNA may have a specific and substantial utility because, e.g., ... it has gene-regulating activity". Utility Examination Guidelines, 66(4) Fed. Reg. 1095 (Jan. 5, 2001).

Applicants note that Y13724 present in 60/125,814 is exactly the same sequence found in Edwards (Y13724 is indicated as AtHAP3b in Edwards in Fig. 3 in the right-most column) the art cited against Applicants.

This begs the question: why does Applicants' priority application allegedly inadequately describe Y13724, but the cited art has a sufficiently adequate description of the same sequence to make this a basis of an obvious rejection? Does the art with the exact same sequence have adequate description, enablement and utility, whereas the disclosure of the sequence in Applicants' disclosure does not?

Although Applicants described a function for SEQ ID NO: 4 and Edwards did not, the Office has stated that "one cannot separate the function of AtHAP3b transcription factor taught by Edwards from its structure" (Office Action mailed 25 February 2009, page 9, ¶2). The same sequence in Edwards has the same slight truncation as in the instant priority application. Its function in the art must be the same as in the priority document? Any useful properties this sequence may have cannot be separated from its structure provided in the art, and thus has the same utility in art and in the priority application. If it were obvious to try to make use of the art-taught sequence, why would Y13724 be sufficiently described in the art such that a plant transformed with it has traits that flow naturally and make the present claims obvious, but insufficiently described in the priority document such that the instantly claimed sequence wasn't fully appreciated by Applicants in March of 1999 in spite of the fact that Applicants proposed transgenic plants and associated utilities, including traits instantly claimed (e.g., "salt or osmotic shock")?

The question of how one "cannot separate the function of the AtHAP3b transcription factor taught by Edwards from its structure", yet perform such function-structure separation with Applicant's identical sequence, has not been addressed by the Examiner. If one cannot separate the function of the AtHAP3b transcription factor from its structure, either the truncated sequence works for Edwards or it does not, and the same function or lack of function must apply equally to the AtHAP3b sequence disclosed by Applicants in 60/125,814. If the function of the truncated sequence is suspect, Edwards taken with Harada cannot make the claimed invention obvious, as the Examiner has diligently maintained. If the slight truncation is irrelevant, then the 60/125,814 priority application provides sufficient guidance, possession and utility. This is one case where a double standard cannot apply; one "cannot separate the function of the AtHAP3b transcription factor [Y13724] taught by Edwards [and by Applicants] from its structure".

Accordingly, Applicants believe priority application 60/125,814, filed 03/23/99, disclose the sequences, plants, traits, and utility that describe the present invention, that the same sequence, Y13724, is found in the art and priority application 60/125,814, that the latter disclosure provides utility for the sequence and plants transformed with it, and that the date of the art and the priority of the instant application are less than one year after the cited art.

Item 5. Double patenting

The Examiner has provisionally rejected claims 62-77 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claim 105 of copending application no. 11/069,255.

Applicants believe the instant amendment of the claims avoids this double patenting rejection

Applicants believe that all other rejections may be presently overcome, and thus respectfully request that this ground of rejection be held in abeyance until patentable subject matter is defined for the present application.

Item 6. Double patenting

Formerly co-pending patent application 10/286,264 has been abandoned.

Accordingly, Applicants respectfully request that the provisional obviousness-type double patenting rejection be withdrawn.

Item 8. Claim rejection, 35 U.S.C. §112, written description

Applicants respectfully traverse the rejection and its supporting remarks.

However, in order to facilitate prosecution in this case Applicants have amended the pending claims, without prejudice or disclaimer.

The disclosure in the multiple sequence alignment in Figures 6A-6F, showing the B domains of the G482 related sequences, indicated consensus residues by boldface. The boldfaced residues in the consensus sequence that appears at the bottom of Figures 6A through 6C in their respective positions are uniquely found in the non-LEC1-like clade. The non-LEC1-like clade is distinguished by a B domain comprising:

Asn-(Xaa)₄-Lys-(Xaa)₃₃₋₃₄-Asn-Gly;

and the G482 subclade is distinguished by a B-domain comprising:

Ser-(Xaa)₉-Asn-(Xaa)₄-Lys-(Xaa)₃₃₋₃₄-Asn-Gly.

Consensus sequences, and their utility in determining function of a sequence, are well known in the art.

It is art recognized that multiple sequence alignments, such as Figures 6A-6F, may be used to provide guidance to understand and identify related sequences. It is art-recognized that with such an alignment, related sequences with similar functions may be identified by comparing evolutionarily conserved residues and conserved domains within polypeptide alignments.

Furthermore, the specification and sequence listing provide numerous closely related sequences that function as does SEQ ID NO: 4.

Since the standard for the written description requirement is that the disclosure of the application “reasonably conveys to the artisan that the inventor had possession at the time”, Applicants have met the

written description requirement and one of skill in the art would clearly understand that the Applicants had possession of the claimed invention.

In light of these amendments, and arguments, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, for lack of written description, be withdrawn.

Item 10. Claim rejection, 35 U.S.C. § 103(a)

Claims 73-104 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Edwards et al (July 1998, *Plant Physiology* 117: 1015-1022) in view of Harada et al (U.S. Patent 6,235,975 B1, filed 24 June 1998).

Applicants respectfully traverse the rejection and its supporting remarks, particularly since Applicants, as they have shown, conceived of the claimed transgenic plants prior to the Edwards 1998 publication.

However, in order to facilitate prosecution in this case Applicants have amended the pending claims, without prejudice or disclaimer.

Neither of the references cited by the Office teaches producing and selecting a transgenic plant exhibiting enhanced yield or increased tolerance to salt or osmotic stress. Applicants therefore submit that the combination of the art fails to disclose the presently claimed methods. There is nothing in the cited art, alone or taken together, that would suggest producing a plant transformed with SEQ ID NO: 4 and selecting for the claimed traits. A person of average skill in the art would not have been motivated to choose from all of the sequences available at the time of the art, amplify and clone the instantly claimed sequence, transform plants, and select for the claimed traits.

Furthermore, as Edwards et al. indicates on page 1010, column 1, “[t]he open reading frame in AtHAP3a is the only one that starts with a Met, suggesting that the ESTs encoding *AtHAP3b*, *AtHAP5a*, and *AtHap5b* are truncated clones.” Thus, according to the Examiner’s own statement, the combination of the art does not teach all of the elements of the instantly claimed invention: “oligonucleotides and a partial sequence [Y13724] are not SEQ ID NO: 14 (sic) or nucleic acid encoding it”.

In view of the amendments to the claims and the arguments presented above, Applicants respectfully request that the rejection under 35 U.S.C. § 103(b) be withdrawn.

CONCLUSION

Applicants believe that no additional fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Mendel Biotechnology, Inc. Deposit Account No. **50-1025**.

Respectfully submitted,
MENDEL BIOTECHNOLOGY, INC.

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